K130268

510(k) Summary
BD ProbeTec™ *Trichomonas Vaginalis* (TV) Q^x Amplified DNA Assay

Applicant BD Diagnostic Systems
7 Loveton Circle
Sparks, MD 21152

Establishment Registration No. 1119779

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Summary Date August 15, 2013

Proprietary Name BD ProbeTec™ *Trichomonas vaginalis* (TV) Q^x Amplified DNA Assay

Generic Name DNA probe, nucleic acid amplification, *Trichomonas vaginalis*

Classification Class II
Classification Name *Trichomonas vaginalis* nucleic acid amplification test system
Regulation Number 21 CFR 866.3860
Product Code OUY

Predicate Device APTIMA Trichomonas vaginalis Assay (K102911)

Device Description

The BD ProbeTec *Trichomonas vaginalis* (TV) Q^x Amplified DNA Assay (TVQ Assay) is based on the simultaneous amplification and detection of target DNA using amplification primers and fluorescently-labeled detector probes. The reagents for SDA are dried in two separate disposable microwells: the Priming Microwell contains the amplification primers, fluorescently-labeled detector probe, nucleotides and other reagents necessary for amplification, while the Amplification Microwell contains the two enzymes (a DNA polymerase and a restriction endonuclease) that are required for SDA. The BD Viper™ System pipettes a portion of the purified DNA solution from each Extraction Tube into a Priming Microwell to rehydrate the contents. After a brief incubation, the reaction mixture is transferred to a corresponding, pre-warmed Amplification Microwell which is sealed to prevent contamination and then incubated in one of the two thermally-controlled fluorescent readers. The presence or absence of *Trichomonas vaginalis* DNA is determined by calculating the peak fluorescence (Maximum Relative Fluorescent Units (MaxRFU) over the course of the amplification process and by comparing this measurement to a predetermined threshold value.

In addition to the fluorescent probe used to detect amplified TV target DNA, a second labeled oligonucleotide is incorporated in each reaction. The Extraction Control (EC) oligonucleotide is labeled with a different dye than that used for detection of the TV specific target and is used to confirm the validity of the extraction process. The EC is dried in the Extraction Tubes and is rehydrated upon addition of the specimen and extraction reagents. At the end of the extraction process, the EC fluorescence is monitored by the BD Viper System and an automated algorithm is applied to both the EC and target-specific signals to report results as positive, negative, or EC failure.

Intended Use

The BD ProbeTec™ *Trichomonas vaginalis* (TV) Q^x Amplified DNA Assay, when tested with the BD Viper™ System in Extracted Mode, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Trichomonas vaginalis* DNA in clinician-collected female endocervical swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and female urine specimens. The assay is indicated for use with asymptomatic and symptomatic females to aid in the diagnosis of trichomoniasis.

Summary and Principles of Operation

When used with the BD Viper System, the BD ProbeTec TV Q^x Amplified DNA Assay involves automated extraction of DNA from clinical specimens through the chemical lysis of cells, followed by binding of DNA to para-magnetic particles, washing of the bound nucleic acid, and elution in an amplification-compatible buffer. When present, TV DNA is then detected by Strand Displacement Amplification (SDA) of the specific target sequence in the presence of a fluorescently-labeled detector probe.

Analytical Performance Characteristics

Limit of Detection (Analytical Sensitivity)

The Limit of Detection (LOD) for the TV Q^x Assay on the BD Viper System was determined for two strains of *T. vaginalis* (one Metronidazole-sensitive and one Metronidazole-resistant) by diluting in specimen matrices (vaginal swab, endocervical swab, and urine) and in clean BD Q^x Swab Diluent to create an LOD panel consisting of six target levels of organism. For each strain and target level, twenty replicates of each panel member were tested on different BD Viper Systems for a total of 60 replicates. LOD was confirmed using 20 replicates at the estimated LOD for each matrix type. The LOD for the TV Q^x Assay in clean BD Q^x Swab Diluent was determined to be 54.5 and 55.5 trichomonads/mL for ATCC Strains 30001 and 50143, respectively. The LOD for urine and swab matrices are presented in **Table 1**. The TV Q^x Assay on the BD Viper System in extracted mode could detect with ≥95% proportion positive four additional ATCC strains (30237, 50144, 30184, and 30185) in urine matrix and three ATCC strains (30185, 30237, and 50144) in vaginal swab specimen matrix at a concentration of 122.1 TV/mL.

Table 1: LoD Estimates for TV Q^x Assay

Specimen Type	ATCC Strain	LOD (TV/mL)
Neat Urine	30001	109.7
	50143	108.2
Vaginal	30001	74.4
	50143	88.4
	30184*	152.8
Endocervical	30001	64.8
	50143	76.2

*LOD for *T. vaginalis* ATCC strain 30184 was determined in vaginal swab specimen matrix only.

Analytical Specificity

The DNA from 54 organisms was extracted on the BD Viper System and tested with the BD ProbeTec TV Q^x Amplified DNA Assay. All potential cross-reactive species were tested at approximately $\geq 1x10^6$ CFU/mL (bacteria and yeast), $\geq 1x10^6$ vp/mL (viral particles), or organisms/mL (viruses and pathogens), except where noted. Results are summarized in **Table 2**.

Table 2: Potential Cross-Reactants

Organism	
Acinetobacter baumannii	*HPV-18*
Actinomyces israelii	*Human Immunodeficiency Virus 1 (HIV-1)*
Atopobium vaginae	*Klebsiella oxytoca*
Bacteroides fragilis	*Lactobacillus acidophilus*
Bifidobacterium bifidum	*Lactobacillus jensenii*
Campylobacter jejuni	*Lactobacillus vaginalis*
Candida albicans	*Listeria monocytogenes*
Candida glabrata	*Mobiluncus curtisii*
Candida parapsilosis	*Moraxella catarrhalis (Branhamella sp.)*
Candida tropicalis	*Mycobacterium smegmatis*
Chlamydia trachomatis	*Mycoplasma genitalium*
Clostridium difficile	*Mycoplasma hominis*
Clostridium perfringens	*Neisseria gonorrhoeae*
Corynebacterium genitalium biovar 1	*Pentatrichomonas hominis*[1]
Cryptococcus neoformans	*Peptostreptococcus anaerobius*
Enterobacter aerogenes	*Prevotella bivia*
Enterobacter cloaceae	*Proteus mirabilis*
Enterococcus faecalis	*Pseudomonas aeruginosa*
Escherichia coli	*Staphylococcus aureus, non-protein A*
Fusobacterium nucleatum	*Staphylococcus aureus, protein-A producing*
Gardnerella vaginalis	*Staphylococcus epidermidis*
Haemophilus ducreyi	*Staphylococcus saprophyticus*
Herpes Simplex Virus Type 1	*Streptococcus pyogenes (Group A)*
Herpes Simplex Virus Type 2	*Streptococcus agalactiae (Group B)*
HPV-6	*Trichomonas tenax*
HPV-11	*Ureaplasma urealyticum*
HPV-16	*Veillonella parvula*

1 Tested at $3.39x10^5$ organisms/mL

It was determined that *Trichomonas tenax* is a cross-reactant at levels above 1.0×10^4 organisms/mL of the TVQ Assay when tested on the BD Viper System. There were no other organisms found to cross-react with the TVQ Assay when tested on the BD Viper System.

Interfering Substances

Potential interfering substances which may be encountered in endocervical, vaginal, and urine specimens were tested in the absence and presence of TV target (223.2 trichomonads/mL from ATCC Strain 30001 in Vaginal Specimens and 165 trichomonads/mL from ATCC Strain 50143 in female urine specimens) and tested with the BD ProbeTec TV Q^x Amplified DNA Assay on the BD Viper System. Results are summarized in **Table 3.**

TABLE 3: POTENTIAL INTERFERING SUBSTANCES

Interpretation	Swab	Urine matrix
No interference observed at levels listed	Whole Blood (≤ 60%) Seminal Fluid Mucus Over the counter vaginal products and contraceptives Hemorrhoidal cream Prescription vaginal treatments Leukocytes ($1x10^6$ cells/mL) Intravaginal hormones	Phenazopyridine Hydrochloride Whole Blood (≤ 1% v/v) Acidic urine (pH 5.0) Alkaline urine (pH 9.0) Horomone pool Analgesic pool Antibiotics Bilirubin Mucus Albumin (≤ 1mg/mL) Glucose Semen (5% v/v) Over the counter deodorant spray and powder Leukocytes ($2.5x10^6$ cells/mL)
May cause Extraction Control (EC) failures	Blood (> 60%)	Not applicable
May cause false negative results	Not applicable	Not applicable

Clinical Performance Characteristics

First void urine specimens, clinician-collected endocervical swab specimens, and self-collected (in a clinical setting) vaginal swab specimens were collected from 1,222 compliant female subjects attending family planning, OB/GYN, and sexually transmitted disease clinics at seven geographically diverse clinical sites in North America. Specimens were collected from subjects presenting with symptoms of trichomoniasis (symptomatic) or from subjects during routine visits to their healthcare provider (asymptomatic). Subjects were excluded from the data analysis due to collection site workflow, opting to withdraw from the study after initially consenting, transport/handling/storage errors, informed consent issues, subjects failing to meet the inclusion/exclusion criteria, collection errors, shipping errors, instrument errors, operating condition excursions or labeling errors. Therefore, the final data analysis included 735 compliant subjects for urine specimens, 832 compliant subjects for vaginal specimens, and 995 compliant subjects for endocervical specimens.

For each compliant subject, clinical specimens were collected in the following order: (1) a first void urine, (2) a patient-collected vaginal swab, (3) three clinician-collected vaginal swabs, and (4) an endocervical swab. The three clinician collected vaginal swabs were used for reference and discrepant testing. The first two of these were randomized, one swab was tested for the Wet Mount (reference method) and the other swab was used for the InPouch TV Culture (reference method). The third swab was used for testing using a commercially available NAAT. The aliquot of neat urine, the self-collected vaginal swab, and the endocervical swab were tested on the BD Viper System in extracted mode with the TVQ assay.

All sensitivity and specificity calculations were based on the total number of BD ProbeTec TVQ Assay results for endocervical, vaginal, and urine specimens, as compared to a composite reference method. Sensitivity and specificity by specimen type (comparing the TVQ Assay with the composite reference method) are presented in **Table 4**. The initial instrument error rate during the clinical study was 0.1%, or 3 indeterminate results out of 2568 tests. The final error rate after repeat testing was performed on indeterminate results was 0.04%, or 1 indeterminate result out of 2568 tests.

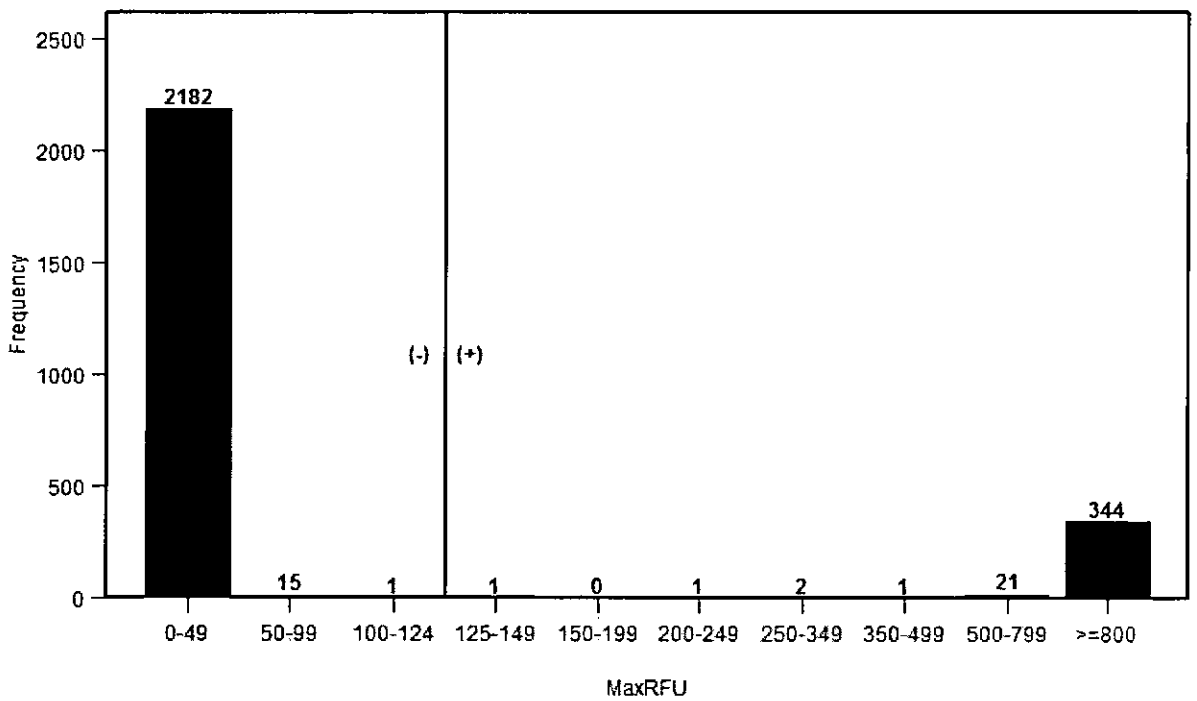
TABLE 4: TVQ ASSAY VS COMPOSITE REFERENCE RESULT CULTURE OF INPOUCH TV CULTURE AND WET MOUNT (BY SPECIMEN TYPE AND SYMPTOMATIC STATUS)

			Performance Compared to Composite Reference			
Specimen Type	**Status**	**n**	**Sensitivity**	**95% C.I.**	**Specificity**	**95% C.I.**
Neat Urine	A	289	93.1% (27/29)	(78.0%, 98.1%)	99.6% (259/260)	(97.9%, 99.9%)
	S	446	96.4% (80/83)	(89.9%, 98.8%)	98.1% (356/363)	(96.1%, 99.1%)
	Total	735	95.5% (107/112)[A]	(90.0%, 98.1%)	98.7% (615/623)[B]	(97.5%, 99.3%)
Vaginal	A	343	93.5% (29/31)	(79.3%, 98.2%)	99.0% (309/312)	(97.2%, 99.7%)
	S	495	100.0% (85/85)	(95.7%, 100.0%)	99.0% (406/410)	(97.5%, 99.6%)
	Total	838	98.3% (114/116)	(93.9%, 99.5%)	99.0% (715/722)[C]	(98.0%, 99.5%)
Endocervical	A	505	92.2% (47/51)	(81.5%, 96.9%)	99.1% (450/454)	(97.8%, 99.7%)
	S	490	98.8% (82/83)	(93.5%, 99.8%)	99.8% (406/407)	(98.6%, 100.0%)
	Total	995	96.3% (129/134)	(91.6%, 98.4%)	99.4% (856/861)[D]	(98.6%, 99.8%)
All Specimen Types Combined	A	1137	92.8% (103/111)	(86.4%, 96.3%)	99.2% (1018/1026)	(98.5%, 99.6%)
	S	1431	98.4% (247/251)	(96.0%, 99.4%)	99.0% (1168/1180)	(98.2%, 99.4%)
	Overall	2568	96.7% (350/362)	(94.3%, 98.1%)	99.1% (2186/2206)	(98.6%, 99.4%)

A = asymptomatic, S = symptomatic

A frequency distribution of the initial MaxRFU values for the TVQ Assay with an assay cutoff of 125 MaxRFU is shown in **Figure A**.

FIGURE A: FREQUENCY DISTRIBUTION OF MAXRFU FOR THE TVQ ASSAY (ALL SPECIMEN TYPES)



Reproducibility

Reproducibility of the BD Viper System using the BD ProbeTec TVQ Assay was evaluated at three test sites on one BD Viper System per site. Each site was provided with four identical reproducibility panels, each of which consisted of samples prepared using either Vaginal Matrix in Q^x Swab Diluent or urine matrix. Each panel member was either left unspiked (0x), or was spiked with known amounts of TV organism (ATCC strain 30001) at 0.3x, 1x, and 3x LOD for each respective specimen matrix. Three replicates of each panel member were tested every day for five days on each BD Viper System. A summary of the reproducibility data for the TVQ Assay is summarized in **Table 5**.

Table 5: Summary of Reproducibility Data on the BD Viper System for the TVQ Assay

					Within Run		Between Run Within Day		Between Day Within Site		Between Site	
Specimen type	Panel	Agreement	95% CI	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Vaginal	Zero	100.0% (89/89)	(95.9%, 100.0%)	3.89	4.02	103.53	2.01	51.64	0.92	23.57	4.69	120.60
	High Negative (0.3X LOD)	43.3% (39/90)	(33.6%, 53.6%)	795.66	814.68	102.39	136.97	17.21	287.34	36.11	190.15	23.90
	Low Positive (1X LOD)	96.7% (87/90)	(90.7%, 98.9%)	1632.07	457.83	28.05	0.00	0.00	0.00	0.00	110.13	6.75
	High Positive (3X LOD)	100.0% (90/90)	(95.9%, 100.0%)	1756.68	297.78	16.95	0.00	0.00	104.51	5.95	260.45	14.83
Urine Matrix	Zero	100.0% (90/90)	(95.9%, 100.0%)	8.70	11.33	130.18	0.00	0.00	0.00	0.00	8.29	95.33
	High Negative (0.3X LOD)	39.3% (35/89)*	(29.8%, 49.7%)	976.96	913.87	93.54	0.00	0.00	0.00	0.00	0.00	0.00
	Low Positive (1X LOD)	92.1% (82/89)*	(84.6%, 96.1%)	1574.67	681.14	43.26	0.00	0.00	0.00	0.00	0.00	0.00
	High Positive (3X LOD)	100.0% (90/90)	(95.9%, 100.0%)	1822.52	364.46	20.00	0.00	0.00	0.00	0.00	172.88	9.49

* Four non-reportable results were due to extraction control failures which caused a reduction in the full number of replicates at one test site.

Conclusion:

The analytical and clinical study results for the BD ProbeTec *Trichomonas vaginalis* (TV) Q^x Amplified DNA Assay support the determination of substantial equivalence in accordance with the intended use as stated in the product labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

EMILY HOWARD
REGULATORY AFFAIRS SPECIALIST
BECTON, DICKINSON AND COMPANY
7 LOVETON CIRCLE
SPARKS MD 21152

August 23, 2013

Re: K130268
Trade/Device Name: BD ProbeTec™ *Trichomonas vaginalis* (TV) Q^{x} Amplified DNA Assay
Regulation Number: 21 CFR 866.3860
Regulation Name: *Trichomonas vaginalis* nucleic acid amplification test system
Regulatory Class: II
Product Code: OUY
Dated: August 12, 2013
Received: August 13, 2013

Dear Ms. Howard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A. Hojvat -S

Sally Hojvat, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k130268

Device Name: BD ProbeTec™ *Trichomonas vaginalis* (TV) Q^x Amplified DNA Assay

Indications for Use:

The BD ProbeTec™ *Trichomonas vaginalis* (TV) Q^x Amplified DNA Assay, when tested with the BD Viper™ System in Extracted Mode, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Trichomonas vaginalis* DNA in clinician-collected female endocervical swab specimens, patient-collected vaginal swab specimens (in a clinical setting), and female urine specimens. The assay is indicated for use with asymptomatic and symptomatic females to aid in the diagnosis of trichomoniasis.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

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